

REMARKS

The specification has been amended at page 6 to correct a minor typographical or editorial error. No new matter has been introduced.

Claims 21-56 and 58-103 are currently pending in light of the amendments above, in which claim 57 has been canceled. Claims 31, 34, 52, 58-60, 68, 72, 73, 81, 84-86, and 94-96 have been amended to correct inadvertent typographical and/or editorial errors in the specified deposit number, as well as in the dependency of claims 31 and 34. No new matter has been introduced. Support for the amendment to claims with respect to the ATCC deposit number can be found in Table 1 at page 8 of the specification.

The Amendment Filed April 26, 2000 Introduced No New Matter

The Amendment filed April 26, 2000 has been objected to under 35 U.S.C. § 132 for allegedly introducing new matter into the disclosure. The Examiner contends that the four paragraphs on the first and second pages of the amendment which were directed to be inserted at page 14, between lines 14 and 15 of the instant specification are not supported by the original disclosure. The Examiner further contends that “[t]here appears to be nothing incorporated by reference in the specification to support the added material” (Office Action, page 2). *objection filed*

As Applicants noted in the April 26, 2000 Amendment at page 12 and in the accompanying Declaration Under 37 C.F.R. 1.68 and M.P.E.P. 608.01(p), the recited passage to be inserted into the specification is from prior Provisional Application No. 60/070,875. *10/16*
Applicants respectfully direct the Examiner’s attention to page 1, lines 4-6 of the instant specification, which states (with emphasis added): *objection*

This application claims priority under 35 U.S.C. § 119(e) to copending US Provisional Application Serial No. 60/070,875 filed January 9, 1998, hereby incorporated by reference. *objection*

Thus, Applicants respectfully submit that the text of prior Provisional Application No. 60/070,875, including the text to be inserted, is incorporated by reference into the instant application. Therefore, Applicants respectfully request that the new matter objection under § 132 be withdrawn.

The Claimed Subject Matter Has Utility Under 35 U.S.C. § 101

Claims 21-103 have been rejected under 35 U.S.C. § 101 for alleged lack of utility.

The Examiner contends that the “claimed polynucleotides are not supported by either a specific and substantial asserted utility or a well-established utility” (Office Action, page 3).

In particular, the Examiner contends at page 3 of the Office Action:

The instant specification discloses that FKBP65 is a FK506 binding protein and confers immunomodulating activity to FK506, rapamycin and cyclosporin A (Page 6, lines 20-26 of the instant specification). Identifying a protein as having homology to FKBP65, does not indicate what function it and thus the encoding polynucleotide might have.

Applicants note that the specification clearly asserts an immunosuppressant-based utility at page 6, lines 29-35, as follows:

The homology to FKBP65 suggests that the protein product of this clone would be useful for¹ screening assays for the discovery of novel immunosuppressant drugs and in the treatment of diseases caused by over-active immune system, particularly those caused by T-cells, such as graft vs. host disease, rheumatoid arthritis, inflammation and osteoarthritis. See, for example, US Patent No. 5,498,597, which describes uses for the novel FKBP-13 polypeptide. The uses described in US Patent No. 5,498,597, hereby incorporated by reference in its entirety, are equally applicable to the translation product of SEQ ID NO:5.

Moreover, the Examiner’s assertion that “There is no specific disease or specific function that is suggested by this homology” implies that a protein is useful only if it can be used for only one disease -- only then is the use “specific”. By this logic, any immunosuppressant drug that could be used for more than one disease would not have a specific utility and would, therefore, be unpatentable. It is well known, as described in U.S. Patent No 5,498,597, cited above, that immunosuppressant drugs can be used in many therapeutic contexts including, for example, various autoimmune diseases and transplantation treatments. A copy of U.S. Patent No. 5,498,597 is attached hereto as Exhibit A.

The Examiner also cites chromosomal localization as an example of a non-specific utility, because it “would apply to every naturally occurring polynucleotide.” Office Action, page 3. Although Applicants respectfully disagree with this conclusion, clearly the

¹ As amended herein, above.

immunosuppressant-based utility is sufficiently specific and is distinguishable from this example. Not every protein binds the FK506 class of immunosuppressant compounds. Certainly, being a member of a class of proteins does not render a particular member of that class unpatentable. A protein's utility need not be unique to only that protein in order to be sufficiently specific to be patentable.

Indeed, the recently published Utility Guidelines support the conclusion that the claimed polynucleotides have a utility that is "specific, substantial, and credible" as defined by the Patent and Trademark Office. In particular, the Utility Guidelines state in the Response to Comment 19:

When a class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same specific, substantial, and credible utility to the assigned protein.

66 F.R. (No. 4) at 1096, January 5, 2001. The polypeptide of SEQ ID NO:6 of the present invention is just such a novel protein assigned to a class of proteins defined "such that members share a specific, substantial, and credible utility." Applicants submit herewith documentary evidence that FK506 binding proteins are a class of useful proteins. In addition to U.S. Patent No. 5,498,597 (Exhibit A), Applicants respectfully direct the Examiner's attention to Galat, A., *Eur J. Biochem.*, (1993) 216:689, which was cited and incorporated by reference at page 6, lines 36-38 of the specification and is attached hereto as Exhibit B; and Coss M.C. et al., *J. Biol. Chem.*, (1995) 270:29336, cited at page 6, lines 21-22 of the specification, and attached hereto as Exhibit C. As summarized in Table 3, at page 695 of Galat, these proteins constitute a well established family with well characterized properties. The structural features that contribute to the common activity of this family of proteins is shown in Figure 5 at page 697 of Galat.

Thus, the immunosuppressant-based utility disclosed in the specification is specific and substantial; and there is no indication in the revised utilities guidelines to the contrary. The revised guidelines appear to lump "throw-away," "insubstantial," and "nonspecific" utilities together as being exemplified by "use of a complex invention as landfill" (Utility Guidelines, 66 FR (No. 4) at 1098, part II.B.2(a)(1)). Clearly, the immunosuppression-based utility disclosed in the specification do not resemble such a "throw away, insubstantial or nonspecific" utility.

Moreover, the disclosed immunosuppressant-based utilities are “credible.” Applicants respectfully emphasize that the manner of making and using an invention disclosed in a specification must be accepted by the PTO “unless there is reason to doubt the objective truth of the statements contained therein.” *In re Marzocchi*, 58 C.C.P.A. 1069, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971); see Utility Guidelines, 66 F.R. (No. 4) at 1098-1099, part II.B.4. Indeed, the Federal Circuit recently affirmed the standard for making a utility rejection as set forth in *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995):

The PTO cannot make this type of rejection... unless it has reason to doubt the objective truth of the statements contained in the written description. See *Brana*, 51 F.3d at 1566, 34 USPQ2d at 1441 (“[T]he PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention’s asserted utility.”) (citations omitted); *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971)... The PTO may establish a reason to doubt an invention’s asserted utility when the written description “suggest[s] an inherently unbelievable undertaking involve[s] implausible scientific principles.” *Brana*, 51 F.3d at 1566, 34 USPQ2D AT 1441, SEE ALSO *In re Eltgroth*, 419 F.2d 918, 164, USPQ 221 (CCPA 1970) (control of aging process).

In re Cortright, 49 U.S.P.Q.2d 1464, 1466 (Fed. Cir. 1999).

In any event, the Federal Circuit has recently articulated the standard for utility in light of *Brenner*:

The threshold of utility is not high: An invention is “useful” under section 101 if it is capable of providing some identifiable benefit. See *Brenner v. Manson*, 383 U.S. 519, 534 (1996); *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992) (“To violate § 101 the claimed device must be totally incapable of achieving a useful result”); *Fuller v. Berger*, 120 F. 274, 275 (7th Cir. 1903) (test for utility is whether invention “is capable of serving any beneficial end”).

Juicy Whip, Inc. v. Orange Bang Inc., 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, ____ (Fed. Cir. 1999).

The Examiner has not met the initial burden of showing that the asserted utility is incredible under either the standard of the courts or of the Utility Guidelines. A person of ordinary skill in the art would find the asserted utilities credible based on the homology between the polypeptides encoded by the claimed polynucleotides and other FK506 binding proteins, as recognized in the Response to Comment 19 of the Utility Guidelines, cited above (66 F.R. (No. 4) at 1096, January 5, 2001). Absent a *prima facie* showing by the Examiner, based on *evidence*, that the asserted utilities are credible, the utility rejection is improper according to the standards set forth by both the Federal Circuit and the Utility Guidelines. However, the Examiner has provided no *evidence* to show that the skilled person would doubt the asserted utility. Therefore, Applicants respectfully request that the rejection under § 101 be withdrawn.

**The Claimed Subject Matter Is Adequately Described
And Enabled Under 35 U.S.C. § 112, First Paragraph**

Written Description And Enablement Regarding 95% Identity

The Examiner has rejected claims 38-51 and 68-80 under 35 U.S.C. § 112, first paragraph, for alleged lack of adequate written description (page 4, item 7) and enablement (page 5, item 9) with respect to 95% identity. The Examiner contends that, while SEQ ID NOS:6 and 8 are adequately described and enabled, variants of these sequences that are 95% identical to them are not.

The test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02.

The Federal Circuit recently re-emphasized the well-settled principle of law that “[t]he written description requirement does not require the applicant ‘to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed,’” *Union Oil Company of California v. Atlantic Richfield Company*, 208 F.3d 989, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000). While the

applicant must “blaze marks on trees,” rather than “simply [provide] the public with a forest of trees;” an Applicant is not required to explicitly describe each of the trees in the forest (*see Union Oil*, 208 F.3d at 1000.) The Court emphasized the importance of *what the person of ordinary skill in the art would understand from reading the specification*; and not whether the specific embodiments had been explicitly described or exemplified. In fact, the court noted that “the issue is whether one of skill in the art could derive the claimed ranges from the patent’s disclosure.” *Union Oil*, 208 F.3d at 1001, emphasis added.

Indeed, Applicants have blazed a trail directly to the claimed polynucleotides. Most importantly, Applicants have provided the skilled person with the detailed structure of the FK506 binding proteins of the present invention. Applicants respectfully urge the Examiner to once again consider the specific properties of the subject protein as disclosed in the specification and available in the art.

First, the specification provides a detailed description of the amino acid sequence of the FK506 binding proteins of SEQ ID NOS:6 and 8. Second, the specification explicitly describes the genus of amino acid sequences having 95% identity to SEQ ID NOS:6 and 8 (*e.g.*, page 12, lines 1-3; page 13, lines 5-6 and 12-13). Thus, from these amino acid sequences alone, the skilled person could readily derive the described genus of 95% identical amino acid sequences. The skilled person would know the amino acid sequence of SEQ ID NOS:6 and 8, and could readily envision myriad alterations (insertions, deletions, and substitutions) to obtain numerous individual species within the genus. Moreover, the specification contains an extensive, detailed description of polypeptide variants of SEQ ID NOS:6 and 8 having 95% identity, at page 11, line 24 to page line 14. This extensive disclosure explicitly describes individual amino acids substitutions, including, for example, exemplary conservative amino acid substitutions described at page 15, line 38 to page 16, line 4:

Moreover, tolerated conservative amino acid substitutions involve replacement of the aliphatic or hydrophobic amino acids Ala, Val, Leu and Ile; replacement of the hydroxyl residues Ser and Thr; replacement of the acidic residues Asp and Glu; replacement of the amide residues Asn and Gln, replacement of the basic residues Lys, Arg, and His; replacement of the aromatic residues Phe, Tyr, and Trp, and replacement of the small-sized amino acids Ala, Ser, Thr, Met, and Gly.

The Examiner acknowledges that a description of a genus may be achieved by recitation of a representative number of member species, or “structural features common to the genus,” and

cites *Regents of the University of California v. Eli Lilly & Co.* 119 F.3d 1559, 1569 in support of this statement (Office Action, page 4). However, it is important to note that the claim at issue in *Lilly* recited the genus of “mammalian insulin cDNA,” without a structural limitation. In contrast, the present claims recite a “structural feature common to the genus”, namely 95% identity to the specified SEQ ID NO. This is just such a structural feature that was lacking in the *Lilly* claims, and which describes the claimed genus, as the Examiner acknowledges may be achieved under *Lilly*. Indeed, there is a precise and readily ascertainable structural relationship between every member of the genus and the described chemical structure of SEQ ID NOS:6 and 8. To require a recitation of these individual members would be an unwarranted elevation of form over substance. The specification clearly conveys to the skilled person that the Applicants had possession of the claimed genus. Thus, the claimed subject matter is adequately described under § 112, first paragraph.

Regarding enablement, the Examiner contends that the skilled person would not be able to make and use nucleic acid molecules encoding polypeptides with 95% identity to SEQ ID NOS:6 and 8 without undue experimentation. Once again, Applicants respectfully direct the Examiner’s attention to the detailed description of polypeptide variants of SEQ ID NOS:6 and 8 having 95% identity, at page 11, line 24 to page line 14. Clearly, the skilled person could readily make such nucleic acid molecules encoding such polypeptide variants, as well as the polypeptides themselves, using well known recombinant techniques, such as those described at pages 14-16 and 20-21.

In addition, as detailed above, it was already recognized in the art by the filing date of the priority application that FK506 binding proteins comprise a large and extensively characterized family of proteins, as summarized in Galat, A., *Eur J. Biochem.*, (1993) 216:689, Exhibit B hereto (see, *e.g.*, Table 3, at page 695). Indeed, the structural features contributing to the characteristic binding activity of this class of proteins had been well characterized, as depicted in Figure 5, at page 697 of Galat.

Therefore, the skilled person had available both the extensive teachings of the structure of the subject polypeptides and the methods of introducing variations provided in the specification; as well as a detailed description in the art of regions of conservation in the protein family. This skilled person would readily be able to align the amino acid sequences of the present invention with those known in the art, determine the regions of conservation, and make alterations that retain either binding activity or antigenicity. Thus, these variants could be used, for example, in

screening assays for immunosuppressants as described at page 6, line 30, or as antigens to obtain antibodies, as described at pages 17-18, useful, for example, in such screening assays. Therefore, it would be routine and would require no undue experimentation for the skilled person, upon reading the specification, to make and use numerous species of the claimed genus.

In summary, the claimed genres are both adequately described and enabled by the specification under § 112, first paragraph. Accordingly, Applicants respectfully request that these rejections be withdrawn.

New Matter Regarding Deposit Accession Number

Claims 52-103 have been rejected under § 112, first paragraph for lack of support for the specified accession number. Applicants thank the Examiner for noting the inadvertent error in the accession number. This rejection has been obviated by the amendments to the claims above providing the correct accession number as described in the specification. Accordingly, Applicants respectfully request that the new matter rejection with respect to the accession number be withdrawn.

The Claims Are Definite Under 35 U.S.C. § 112, Second Paragraph

Claim 57 has been rejected under § 112, second paragraph for lack of sufficient antecedent basis with respect to the limitation “(e)”. Applicants thank the Examiner for noting this inadvertent error. This rejection has been obviated by the cancellation of claim 57, above. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph be withdrawn.



Conclusion

Applicants respectfully request that the amendments and remarks of the present response be entered and made of record in the present application. The application is believed to be in condition for allowance. Early notice to that effect is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution, the undersigned can be reached at the telephone number indicated below. If a fee is required in connection with this paper, please charge Deposit Account No. 08-3425 for the appropriate amount.

Respectfully submitted

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Appendix - Pending Claims

21. An isolated nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of:

- (a) a nucleotide sequence encoding amino acid residues 1 to 574 of SEQ ID NO:6;
- (b) a nucleotide sequence encoding amino acid residues 2 to 574 of SEQ ID NO:6;
- (c) a nucleotide sequence encoding amino acid residues 25 to 574 of SEQ ID NO:6;
- (d) a nucleotide sequence encoding amino acid residues 1 to 388 of SEQ ID NO:8; and
- (e) a nucleotide sequence that is the complement of (a), (b), (c), or (d).

22. The nucleic acid molecule of claim 21 comprising a nucleotide sequence according to (a).

23. The nucleic acid molecule of claim 21 comprising a nucleotide sequence according to (b).

24. The nucleic acid molecule of claim 21 comprising a nucleotide sequence according to (c).

25. The nucleic acid molecule of claim 21 comprising a nucleotide sequence according to (d).

26. The nucleic acid molecule of claim 21 comprising a nucleotide sequence according to (e).

27. The nucleic acid molecule of claim 22 comprising nucleotides 130 to 1851 of SEQ ID NO:5.

28. The nucleic acid molecule of claim 22 comprising nucleotides 3 to 1166 of SEQ ID NO:7.
29. The nucleic acid molecule of claim 21 comprising a nucleotide sequence heterologous to SEQ ID NO:5.
30. The nucleic acid molecule of claim 29, wherein said heterologous nucleotide sequence encodes a polypeptide heterologous to SEQ ID NO:6.
31. (Amended) The nucleic acid molecule of claim [29] 30, wherein said heterologous polypeptide is an Fc domain of immunoglobulin.
32. A recombinant vector comprising the nucleic acid molecule of claim 21.
33. The recombinant vector of claim 32, wherein the nucleic acid molecule is operably associated with a regulatory element that controls expression of said nucleic acid molecule.
34. (Amended) A recombinant host cell comprising the vector of claim [21] 32.
35. A recombinant host cell comprising the nucleic acid molecule of claim 21 operably associated with a regulatory element that controls expression of said nucleic acid molecule.
36. A method of producing a polypeptide encoded by the nucleic acid molecule of claim 21, comprising:
- (a) culturing a host cell comprising said nucleic acid molecule under conditions suitable to produce said polypeptide; and
 - (b) recovering said polypeptide from the culture.
37. A composition comprising the nucleic acid molecule of claim 21 and a pharmaceutically acceptable carrier.

38. An isolated nucleic acid molecule encoding a first amino acid sequence at least 95% identical to the entire length of a second amino acid sequence selected from the group consisting of:

- (a) an amino acid sequence encoding amino acid residues 1 to 574 of SEQ ID NO:6,
- (b) a nucleotide sequence encoding amino acid residues 2 to 574 of SEQ ID NO:6,
- (c) an amino acid sequence encoding amino acid residues 25 to 574 of SEQ ID NO:6, and
- (d) an amino acid sequence encoding amino acid residues 1 to 388 of SEQ ID NO:8;

wherein % identity is determined using the Bestfit algorithm.

39. The nucleic acid molecule of claim 38 that encodes an amino acid sequence at least 95% identical to a second amino acid sequence according to (a).

40. The nucleic acid molecule of claim 38 that encodes an amino acid sequence at least 95% identical to a amino acid sequence according to (b).

41. The nucleic acid molecule of claim 38 that encodes an amino acid sequence at least 95% identical to a second amino acid sequence according to (c).

42. The nucleic acid molecule of claim 38 that encodes an amino acid sequence at least 95% identical to a second amino acid sequence according to (d).

43. The nucleic acid molecule of claim 41 that comprises a nucleotide sequence heterologous to SEQ ID NO:5.

44. The nucleic acid molecule of claim 43, wherein said heterologous nucleotide sequence encodes a polypeptide heterologous to SEQ ID NO:6.

45. The nucleic acid molecule of claim 44, wherein said heterologous polypeptide is an Fc domain of immunoglobulin.

46. A recombinant vector comprising the nucleic acid molecule of claim 41.

47. The recombinant vector of claim 46, wherein the nucleic acid molecule is operably associated with a regulatory element that controls expression of said nucleic acid molecule.

48. A recombinant host cell comprising the vector of claim 46.

49. A recombinant host cell comprising the nucleic acid molecule of claim 41 operably associated with a regulatory element that controls expression of said nucleic acid molecule.

50. A method of producing a polypeptide encoded by the nucleic acid molecule of claim 41, comprising:

- (a) culturing a host cell comprising said nucleic acid molecule under conditions suitable to produce said polypeptide; and
- (b) recovering said polypeptide from the culture.

51. A composition comprising the nucleic acid molecule of claim 41 and a pharmaceutically acceptable carrier.

52. (Amended) An isolated nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of:

- (a) a nucleotide sequence encoding the full-length polypeptide encoded by the cDNA contained in clone HSYBM46 as deposited with the ATCC as accession number [209293] 209193;
- (b) a nucleotide sequence encoding the full-length polypeptide, lacking the N-terminal methionine, which is encoded by the cDNA contained in clone HSYBM46 as deposited with the ATCC as accession number [209293] 209193;

(c) a nucleotide sequence encoding the secreted portion of the polypeptide encoded by the cDNA contained in clone HSYBM46 as deposited with the ATCC as accession number [209293] 209193; and

(d) a nucleotide sequence that is the complement of (a), (b), or (c).

53. The nucleic acid molecule of claim 52 comprising a nucleotide sequence according to (a).

54. The nucleic acid molecule of claim 52 comprising a nucleotide sequence according to (b).

55. The nucleic acid molecule of claim 52 comprising a nucleotide sequence according to (c).

56. The nucleic acid molecule of claim 52 comprising a nucleotide sequence according to (d).

57. (Canceled).

58. (Amended) The nucleic acid molecule of claim 52 comprising the nucleotide sequence of the cDNA, as contained in clone HSYBM46, that encodes the secreted form of the polypeptide encoded by clone HSYBM46, which clone was deposited with the ATCC as accession number [209293] 209193.

59. (Amended) The nucleic acid molecule of claim 52 comprising a nucleotide sequence heterologous to the cDNA contained in clone HSYBM46 as deposited with the ATCC as accession number [209293] 209193.

60. (Amended) The nucleic acid molecule of claim 59, wherein said heterologous nucleotide sequence encodes a polypeptide heterologous to the polypeptide encoded by the cDNA contained in clone HSYBM46 as deposited with the ATCC as accession number [209293] 209193.

61. The nucleic acid molecule of claim 60, wherein said heterologous polypeptide is an Fc domain of immunoglobulin.

62. A recombinant vector comprising the nucleic acid molecule of claim 52.

63. The recombinant vector of claim 62, wherein the nucleic acid molecule is operably associated with a regulatory element that controls expression of said nucleic acid molecule.

64. A recombinant host cell comprising the vector of claim 52.

65. A recombinant host cell comprising the nucleic acid molecule of claim 52 operably associated with a regulatory element that controls expression of said nucleic acid molecule.

66. A method of producing a polypeptide encoded by the nucleic acid molecule of claim 52, comprising:

- (a) culturing a host cell comprising said nucleic acid molecule under conditions suitable to produce said polypeptide; and
- (b) recovering said polypeptide from the culture.

67. A composition comprising the nucleic acid molecule of claim 52 and a pharmaceutically acceptable carrier.

68. (Amended) An isolated nucleic acid molecule encoding a first amino acid sequence at least 95% identical to the entire length of a second amino acid sequence selected from the group consisting of:

- (a) the amino acid sequence of the full-length polypeptide encoded by the cDNA contained in clone HSYBM46 as deposited with the ATCC as accession number [209293] 209193,

(b) the amino acid sequence of the full-length polypeptide, lacking the N-terminal methionine, which is encoded by the cDNA contained in clone HSYBM46 as deposited with the ATCC as accession number [209293] 209193, and

(c) the amino acid sequence of the secreted portion of the polypeptide encoded by the cDNA contained in clone HSYBM46 as deposited with the ATCC as accession number [209293] 209193;

wherein % identity is determined using the Bestfit algorithm.

69. The nucleic acid molecule of claim 68 encoding an amino acid sequence at least 95% identical to a second amino acid sequence according to (a).

70. The nucleic acid molecule of claim 68 encoding an amino acid sequence at least 95% identical to a second amino acid sequence according to (b).

71. The nucleic acid molecule of claim 68 encoding an amino acid sequence at least 95% identical to a second amino acid sequence according to (c).

72. (Amended) The nucleic acid molecule of claim 71 that comprises a nucleotide sequence heterologous to the cDNA contained in clone HSYBM46 as deposited with the ATCC as accession number [209293] 209193.

73. (Amended) The nucleic acid molecule of claim 72, wherein said heterologous nucleotide sequence encodes a polypeptide heterologous to the polypeptide encoded by the cDNA contained in clone HSYBM46 as deposited with the ATCC as accession number [209293] 209193.

74. The nucleic acid molecule of claim 73, wherein said heterologous polypeptide is an Fc domain of immunoglobulin.

75. A recombinant vector comprising the nucleic acid molecule of claim 71.

76. The recombinant vector of claim 75, wherein the nucleic acid molecule is operably associated with a regulatory element that controls expression of said nucleic acid molecule.

77. A recombinant host cell comprising the vector of claim 75.

78. A recombinant host cell comprising the nucleic acid molecule of claim 71 operably associated with a regulatory element that controls expression of said nucleic acid molecule.

79. A method of producing a polypeptide encoded by the nucleic acid molecule of claim 71, comprising:

- (a) culturing a host cell comprising said nucleic acid molecule under conditions suitable to produce said polypeptide; and
- (b) recovering said polypeptide from the culture.

80. A composition comprising the nucleic acid molecule of claim 71 and a pharmaceutically acceptable carrier.

81. (Amended) An isolated nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of:

- (a) a nucleotide sequence encoding the polypeptide encoded by the cDNA contained in clone HFKBC47 as deposited with the ATCC as accession number [209293] 209193; and
- (b) a nucleotide sequence that is the complement of (a).

82. The nucleic acid molecule of claim 81 comprising a nucleotide sequence according to (a).

83. The nucleic acid molecule of claim 81 comprising a nucleotide sequence according to (b).

84. (Amended) The nucleic acid molecule of claim 82 comprising the nucleotide sequence of the cDNA, as contained in clone HFKBC47, that encodes the polypeptide encoded by clone HFKBC47, which clone was deposited with the ATCC as accession number [209293] 209193.

85. (Amended) The nucleic acid molecule of claim 81 comprising a nucleotide sequence heterologous to the cDNA contained in clone HFKBC47 as deposited with the ATCC as accession number [209293] 209193.

86. (Amended) The nucleic acid molecule of claim 81, wherein said heterologous nucleotide sequence encodes a polypeptide heterologous to the polypeptide encoded by the cDNA contained in clone HFKBC47 as deposited with the ATCC as accession number [209293] 209193.

87. The nucleic acid molecule of claim 86, wherein said heterologous polypeptide is an Fc domain of immunoglobulin.

88. A recombinant vector comprising the nucleic acid molecule of claim 81.

89. The recombinant vector of claim 88, wherein the nucleic acid molecule is operably associated with a regulatory element that controls expression of said nucleic acid molecule.

90. A recombinant host cell comprising the vector of claim 88.

91. A recombinant host cell comprising the nucleic acid molecule of claim 81 operably associated with a regulatory element that controls expression of said nucleic acid molecule.

92. A method of producing a polypeptide encoded by the nucleic acid molecule of claim 81, comprising:

- (a) culturing a host cell comprising said nucleic acid molecule under conditions suitable to produce said polypeptide; and
- (b) recovering said polypeptide from the culture.

93. A composition comprising the nucleic acid molecule of claim 81 and a pharmaceutically acceptable carrier.

94. (Amended) An isolated nucleic acid molecule encoding a first amino acid sequence at least 95% identical to the entire length of an amino acid sequence of the polypeptide encoded by the cDNA contained in clone HFKBC47 as deposited with the ATCC as accession number [209293] 209193; wherein % identity is determined using the Bestfit algorithm.

95. (Amended) The nucleic acid molecule of claim 94 that comprises a nucleotide sequence heterologous to the cDNA contained in clone HFKBC47 as deposited with the ATCC as accession number [209293] 209193.

96. (Amended) The nucleic acid molecule of claim 95, wherein said heterologous nucleotide sequence encodes a polypeptide heterologous to the polypeptide encoded by the cDNA contained in clone HFKBC47 as deposited with the ATCC as accession number [209293] 209193.

97. The nucleic acid molecule of claim 96, wherein said heterologous polypeptide is an Fc domain of immunoglobulin.

98. A recombinant vector comprising the nucleic acid molecule of claim 94.

99. The recombinant vector of claim 98, wherein the nucleic acid molecule is operably associated with a regulatory element that controls expression of said nucleic acid molecule.

100. A recombinant host cell comprising the vector of claim 98.

101. A recombinant host cell comprising the nucleic acid molecule of claim 94 operably associated with a regulatory element that controls expression of said nucleic acid molecule.

102. A method of producing a polypeptide encoded by the nucleic acid molecule of claim 94, comprising:

- (a) culturing a host cell comprising said nucleic acid molecule under conditions suitable to produce said polypeptide; and
- (b) recovering said polypeptide from the culture.

103. A composition comprising the nucleic acid molecule of claim 94 and a pharmaceutically acceptable carrier.